Dear Dr Leiden

I write further to my letter of 12 October on behalf of the Health and Social Care Committee of the House of Commons, in connection with the Committee’s inquiry into access for NHS patients to drugs where their pricing means they are not considered cost effective and, therefore, a good use of NHS or taxpayer resources.

As foreseen in my earlier letter, the Committee has instructed me to request the following documents and evidence to assist it with its inquiry:

- Vertex’s final submission to NICE for Orkambi, including details of the price at which you proposed to make Orkambi available to the NHS and the evidence submitted in support of the drug’s clinical benefit;

- Following NICE’s decision not to recommend the provision of Orkambi by the NHS at the price offered, any further formal offers to NICE either to reduce the price or to provide further evidence of greater clinical benefit beyond that evidenced in your previous submission;

- Full details of all formal offers made to NHS England, including the February 2018 offer, for the provision of drugs for the treatment of cystic fibrosis, including the prices and quantities of the drugs offered, and the overall total amount of money being sought from the NHS over a 5, 10 and 15 year timeframe;
· Any formal updated offers made following your initial proposal in February 2018 which improved the prices and/or the terms of the proposal;

· Evidence in support of your public statement that you have offered the NHS in England the lowest price for your drugs of any country in the world. This should take the form of the specific pricing and commercial arrangements you have entered into in each country where Vertex sells its medicines.

As previously indicated, the Committee would expect to publish any documents received, and it will use the formal powers granted to it by the House of Commons to require the provision of those documents if they are not provided in response to this request.

The Committee expects to receive the documents it has requested by Friday 30 November. Should an agreement between Vertex, NICE and NHS England have been reached by that date for reimbursement at a level the NHS would recognise as cost effective, I would not expect the Committee to publish any documents it has received or to progress its inquiry any further at the present time.

I am writing in similar terms to NICE and to NHS England to request the provision of relevant documentation which they hold.

Yours sincerely,

[Signature]

Dr Sarah Wollaston MP
Chair of the Committee
Letter by email

7 November 2018

Dear Simon

I write further to my letter of 12 October on behalf of the Health and Social Care Committee of the House of Commons, in connection with its inquiry into drugs which may potentially provide patient benefit but where their pricing means they are not considered cost effective and, therefore, a good use of NHS or taxpayer resources.

As foreseen in my earlier letter, the Committee has instructed me to request the following documents and evidence:

- The full formal response by NHS England to Vertex’s portfolio proposal of February 2018 for drugs for the treatment of cystic fibrosis;
- Full details of any formal update to that proposal made since then.

As previously indicated, the Committee would expect to publish any documents received, and it will use the formal powers granted to it by the House of Commons to require the provision of those documents if they are not provided in response to the request.

The Committee expects to receive the documents it has requested by Friday 30 November. Should an agreement between Vertex, NICE and NHS England have been reached by that date for reimbursement at a level the NHS would recognise as cost effective, I would not expect the Committee to publish any documents it has received or to progress its inquiry any further at the present time.

I am writing in similar terms to Vertex Pharmaceuticals and to NICE to request the provision of relevant documentation which they hold.

Yours sincerely,

Dr Sarah Wollaston MP
Chair of the Committee
Dear Andrew,

I write further to my letter of 12 October on behalf of the Health and Social Care Committee of the House of Commons in connection with its inquiry into drugs which may potentially provide patient benefit but where their pricing means they are not considered cost effective, and, therefore, a good use of NHS or taxpayer resources.

As foreseen in my earlier letter, the Committee has instructed me to request the following documents and evidence:

- The unredacted assessment of the clinical and cost effectiveness of the drugs presented to the NICE appraisal Committee, and the Committee’s findings.

As previously indicated, the Committee would expect to publish any documents received, and it will use the formal powers granted to it by the House of Commons to require the provision of those documents if they are not provided in response to the request.

Also as foreseen in my earlier letter, the Committee requests from NICE a memorandum providing the following information:

- What the scale of difference between the company’s submitted price and a cost-effective price is, and how this scale of difference compares with typical company submissions;

- The guidance and signposting available to companies in the event of a negative appraisal being consulted on;

- Examples of the response of other companies in a similar circumstance that have led to positive guidance being reached, with the revisions proposed;

- How NICE is able to respond in the public interest if the conduct of a company does not support the completion of a cost effectiveness assessment.
The Committee expects to receive the documents detailed in this request by Friday 30
November. Should an agreement between Vertex, NICE and NHS England have been
reached by that date for reimbursement at a level the NHS would recognise as cost
effective, I would not expect the Committee to publish any documents it has received
containing commercially sensitive information or to progress its inquiry any further at the
present time.

I am writing in similar terms to Vertex Pharmaceuticals and to NHS England to notify them
of the Committee's intention to request the provision of relevant documentation which
they hold.

Yours sincerely,

Dr Sarah Wollaston MP
Chair of the Committee